K060149

FEB 3 2006

Appendix V

Summary Information

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

Device Name: Sunipan

Common Name(s): Digital imaging device

Classification Name(s): Digital imaging device

Manufacturer: **Suni Medical Imaging, Inc.**
6840 Via Del Oro, Suite 160
San Jose, CA 95119
408.227.6698
408.227.9949

Registration Number: 3003952803

Classification(s):

Sec. 872.1800 Extraoral source x-ray system.
(a) Identification. An extraoral source x-ray system is an AC-powered device that produces x-rays and is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The x-ray source (a tube) is located outside the mouth. This generic type of device may include patient and equipment supports and component parts.

(b) Classification. Class II.

Device Class: Class II for the requested indications
Classification Panel: Dental Devices Panel
Product Code(s): 90-EHD

Equivalent Predicate Device:
Suni Medical Imaging, Inc. believes that the Sunipan Imaging System is substantially equivalent to the following legally marketed Digital imaging device(s):

1. K051664 Scan300fp/Retropan
2. K043557 PC 1000

Equivalency can be seen with respect to place of manufacture, physical appearance, functional testing, material certification, instructions for use and indications for use. A feature comparison chart follows this section.

Device Description:
Axial rotation x-ray source (PC-1000). The PC-1000 panoramic X-ray machine portion of the Sunipan Imaging System generates the required ionizing radiation (x-rays) This unit is identical to the PC-1000 model supplied directly by Panoramic Corporation for use with standard x-ray film. The Sunipan Imaging System combines this base x-ray unit with an available aftermarket digital imaging sensor, creating a filmless digital imaging system.

Digital Image Sensor (Scan300fp/Retropan) is a high speed x-ray camera tailored for dental panographic applicatrions. Originally designed and cleared for retro-conversion of existing standard panographic x-ray units. The sensor system utilizes direct conversion technology which offers a number of benefits over CCD technology. The images obtained may be reviewed and adjusted after exposure to focus on different layers or areas of clinical interest.

The sensor utilizes Ajat software .

Accessories:
1. Disposable Mouth Pieces.
2. Positioning Aids.

Indications for Use:
For diagnostic radiographic use in dental, oral surgery, and orthodontic practices

Company Contact:
Mr. F. A. Bettencourt
Suni Medical Imaging, Inc.
6840 Via Del Oro, Suite 160
San Jose, CA 95119
408.227.6698
408.227.9949

Submission Correspondent:
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 2006

Suni Medical Imaging, Inc.
% Mr. Morten Simon Christensen
Staff Engineer & FDA Office Coordinator
Medical Device Services
Underwriters Laboratories, Inc.
455 E. Trimble Road
SAN JOSE CA 95131

Re: K060149
Trade/Device Name: SuniPan Imaging Systems & Accessories
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: January 19, 2005
Received: January 20, 2005

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number : K060149

Device Name(s): SuniPan Imaging System & Accessories

Indications for Use Statement(s):

For diagnostic radiographic use in dental, oral surgery, and orthodontic practices.

Prescription Use X OR Over-The-Counter Use

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060149

(Per 21 CFR 801.109) (Optional format 1-2-96)